## REMARKS

Claims 1-34 are pending and claims 1-8, 12, 15-16, 21-28, 30 and 33 have been examined on the merits. Claims 1-2, 8, 12, 15-16, 21-24, 28, 30 and 33 are amended hereinabove, claims 3-7 are cancelled and claims 35-37 are added. Support for the new claims can be found in the subject matter of original claims 1, 3 and 24. The specification and the drawings have also been amended hereinabove to correct minor typographical errors and inconsistencies. No new matter has been added.

In the Office Action, the specification is objected to and the claims are objected to and rejected as follows:

1. The specification is objected to because of inconsistencies with the Sequence Listing;
2. Claims 1 is objected to because of the incorrect sequence identification number;
3. Claims 1, 3, 17, 21-23, 27-28 and 30 are objected to for the presence of the pronoun "its";
4. Claim 1 and claims dependent thereof are objected to for improperly recite the plural form of "fragments" etc.;
5. Claim 15 is objected to for informalities;
6. Claim 24 is objected to because formula (I) and formula (II) insertion does not correspond to the correct location;
7. Claims 1-8, 12, 15-16, 21-28, 30 and 33 are rejected under 35 U.S.C. § 112, ¶ 2, for allegedly being indefinite;
8. Claim 15 is rejected under 35 U.S.C. § 112, ¶ 1 for allegedly containing subject matter which was not described in the specification;

9. Claims 1-8, 12, 16, 21-28, 30 and 33 are rejected under 35 U.S.C. § 112, ¶ 1 for allegedly failing to comply with the written description requirement;

10. Claims 1-8, 16, 21-23, 27-28, 30 and 33 are rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by WO 03/072608 (hereinafter "the WO '608"); and

11. Claims 1-8, 16, 21-28, 30 and 33 are rejected under 35 U.S.C. § 103(a) for allegedly being unpatentable over WO '608 in view of U.S. Patent No. 7,390,828 to Paganelli et al. (hereinafter "Paganelli") in view of U.S. Patent No. 7,425,317 to De Santis et al. (hereinafter "De Santis").

Applicants respectfully traverse the objections and rejections.

**Objections to the Specification**

The specification and the drawings (Figures 17 and 18) are amended hereinabove to correct minor inconsistencies. Replacement sheets of Figures 17 and 18 are submitted herewith to provide the correct sequence identifier consistently with the specification. Thus, with this amendment the objections to the specification are rendered moot.

**Objections to the Claims**

Claims 1-2, 8, 12, 15-16, 21-24, 28, 30 and 33 are amended hereinabove rendering the objections to the claims moot.

**Rejection under 35 U.S.C. § 112, ¶ 2**

Claims 3-7 are cancelled hereinabove and claims 1-2, 8, 12, 15-16, 21-24, 28, 30 and 33 are amended rendering the rejection under 35 U.S.C. § 112, ¶ 2 moot. Regarding claim 25, Applicants did not intend to write "disuccinimidyl" before "suberate". Accordingly, Applicants respectfully request that this rejection be reconsidered and withdrawn.

**Rejection of claim 15**

Claim 15 is rejected under 35 U.S.C. § 112, ¶ 1 for allegedly containing subject matter which was not described in the specification. The Examiner has taken the position that Applicants have not fulfilled the provisions under 37 C.F.R. §§ 1.808(a)(2) and 1.804(b).

Applicants submit hereinbelow the following statement as required under 37 C.F.R. § 1.808(a)(2):

"Applicants assure that all the restrictions imposed by the depositor and the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent in the present U.S. patent application." (37 C.F.R. § 1.808(a)(2)).

On the other hand 37 C.F.R. § 1.804(b) states:

> (b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed. (Emphasis added).

The effective filing date of the present application is the filing date of the priority application RM2004A000105 filed February 27, 2004. The original deposit of biological material has been made on November 12, 2003, which is prior to the effective filing date of the present application. Thus, Applicants submit that the provision of 37 C.F.R. § 1.804(b) does not apply.

In light of these remarks, Applicants respectfully request that the rejection of claim 15 be reconsidered and withdrawn.

**Rejection under 35 U.S.C. § 112, ¶ 1**

Claims 3-7 are cancelled hereinabove and claims 1, 8, 12, 21-23, 27-28, 30 and 33 are amended hereinabove. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 112, ¶ 1 be reconsidered and withdrawn.

**Rejection under 35 U.S.C. § 102(b)**

The presently claimed invention is directed to an isolated anti-human tenascin antibody comprising a light chain variable region of SEQ ID NO:2 and a heavy chain variable region of SEQ ID NO:4 (*e.g.*, page 5 lines 7-10 and Figures 17-18).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaa Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). WO '608 does not disclose each and every element as set forth in the claims and therefore it is not an anticipatory reference for the claimed subject matter. SEQ ID NO:1 and SEQ ID NO: 2 described in WO '608 do not correspond to sequences SEQ ID NO: 2 and SEQ ID NO:4 presently claimed (*e.g.*, compare figures 17 and 18 of the present application with figures 10 and 11 of WO '608). In fact, the present application and WO '608 are directed to two different antibodies: ST2485 is the antibody presently claimed and ST2146 is the antibody described in WO '608 (*e.g.*, present specification page 3, last paragraph, page 4, second paragraph, pages 22-23 and figures 13 14, 14a, 15, and 16).

Moreover, the two antibodies are produced by two different hybridoma cell lines: ST2146 described in the WO '608 is produced by the hybridoma cell line cST2146, which has been deposited on January 29, 2002 with Advanced Biotechnology Center, Genoa with assigned Accession No. PD02003 (*e.g.*, page 10 of WO '608, lines 7-10).

On the contrary, the presently claimed antibody, ST2485, is produced by the hybridoma cell line cST2485 deposited on November 12, 2003 at the Centro of Biotecnologie Avanzate, Genoa, with assigned Accession No. PD03003.

Accordingly, it is respectfully submitted that for all of these reasons WO '608 does not anticipate the claimed subject matter and withdrawal of the rejection under 35 U.S.C. § 102(b) is

respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

As set forth above, the presently claimed invention differs from the antibody described in WO '608 and nowhere the WO '608 suggests how to arrive at the presently claimed invention.

Further, the ST2146 and the presently claimed antibody exhibit a surprising *in vitro* and *in vivo* additive effect with regard to binding to tenascin (*e.g.*, page 4, second paragraph, figures 13-16 and pages 22-23). This result was unpredictable and thus non-obvious.

Paganelli does not supply for WO '608 because it suffers from the same deficiencies. Specifically, Paganelli describes modified biotins useful for the preparation of conjugates with radionuclides for use in human and animal diagnostics and therapy (*e.g.*, col. 1, lines 11-15). However, Paganelli is completely silent with regard to the presently claimed antibody.

De Santis only provides for modified avidins for the diagnosis of tumors (*e.g.*, col. 1, lines 18-21 and Figures 3 and 4). One the antibodies labeled with the modified avidin is the antibody ST2146 described in the WO '608, which is not the presently claimed invention.

Accordingly, the combination of WO '608 with Paganelli and De Santis does not disclose all of the claimed limitations and therefore would not have rendered obvious the claimed subject to one skilled in the art.

Thus, for all of these reasons Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

**Conclusion**

This response is being filed within the shortened statutory period for response, thus, no fees are believed to be due. If, on the other hand, it is determined that further fees are necessary or any overpayment has been made, the Commissioner is hereby authorized to debit or credit such sum to

Deposit Account No. 02-2275.

Pursuant to 37 C.F.R. § 1.136(a), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time of its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated herewith is to be charged to the above-mentioned deposit account.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted

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